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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,756	05/26/2004	**Arthur G. Huggard**	713629.351	3755

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EXAMINER	
BURGESS, JOSEPH D	

ART UNIT	PAPER NUMBER
4114	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/709,756	HUGGARD ET AL.	
	Examiner	Art Unit	
	JOSEPH BURGESS	4114	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 May 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. This action is in reply to application 10709756 filed on 05/26/2004.

2. Claims 1-39 are currently pending and have been examined.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 6-9, 21, 22, and 28-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 6-9, 21, and 28 recite "edit specification" but it is unclear to what edit specification the applicant is referring. Claim 22 is dependent on claim 21 and is therefore rejected for the same reason. Claims 29-34 are dependent on claim 28 and are therefore rejected for the same reason. Additionally, claim 6 recites "receiving clinician input in response to a determination that the entered data does not conform to the corresponding edit specification" but is unclear what happens if the data does conform to the corresponding edit specification. Claims 7-9 are dependent on claim 6 and are therefore rejected for the same reason.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1-11 and 19-25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

7. Claims 1-11 and 19-25 are directed to a method. Based on Supreme Court precedent and recent Federal Circuit decisions, the Office's guidance to examiners is that a §101 process must (1) be tied to a machine or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. In re Bilski et al, 88 USPQ 2d 1385 CAFC (2008); Diamond v. Diehr, 450 U.S. 175, 184 (1981); Parker v. Flook, 437 U.S. 584, 588 n.9 (1978); Gottschalk v. Benson, 409 U.S. 63, 70 (1972); Cochrane v. Deener, 94 U.S. 780,787-88 (1876). Additionally, claim 1 recites "offering…using an offer communication technology" and "recording…in an electronic database". These machines are considered to be tied to insignificant, post-solution activities and therefore do not provide the structure needed to overcome the §101 issue.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Examiner's Note: The Examiner has pointed out particular references contained in the prior art of record within the body of this action for the convenience of the Applicant. Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply. Applicant, in preparing the response, should consider fully the entire reference as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the Examiner.

9. Claims 1 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Hume (WO 2001/25938 A1).

10. Claim 1:

Hume, as shown, discloses the following limitations:

- *entering clinical trial data directly by an examining clinician using a remote computing device* (see at least page 9, lines 11-22, i.e. remote user enters clinical trial data from a remote site)*;*
- *determining whether the remote computing device is communicatively coupled to a central server* (see at least page 3, lines 16-22, i.e. remote site detects if a network connection is present with central site)*;*
- *transmitting the clinical trial data from the remote computing device to the central server in response to a determination that the remote computing device is communicatively coupled to the central server* (see at least page 3, lines 1-22, i.e. data is transmitted to central site if remote site detects network connection)*;*
- storing the data in a secure store within the remote computing device in response to a determination that the remote computing device is not communicatively coupled to the central server (see at least page 6, lines 15-26, i.e. if network connection is not established, remote site can store data).

11. Claim 10:

Hume, as shown, discloses the following limitations:

- *employing a client certificate to secure the clinic trial data in the secure store of the remote computing system* (see at least page 7, line 8 – page 9, line 10, i.e. remote users must log into system with user id and password, remote users are assigned roles that limit their access rights, and patient data packets use public and private keys to protect a patient's privacy)*;*
- *associating the client certificate with the clinical trial data to secure the clinical trial data from unauthorized access* (see at least page 7, line 8 – page 9, line 10, i.e. remote users must log into system with user id and password, remote users are assigned roles that limit their access rights, and patient data packets use public and private keys to protect a patient's privacy).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hume (WO 2001/25938 A1) in view of Becker, et al. (US 2002/0019749 A1).

15. **Claim 2:**

Hume discloses the limitations as shown in the rejections above. Hume does not explicitly disclose the limitation of *digitizing an image of hand drawn information entered by the clinician on the remote computing device*. However, in at least paragraphs 0039 and 0080, Becker discloses a clinician can enter a handwriting image on a handheld computer tablet using pen strokes. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data transferring method of Hume with the digitized handwriting technique of Becker because it allows the process to, "...automate healthcare administrative tasks such as completion of forms, requisitions, transmittal memos, etc. to improve the accuracy of information and reduce errors in the provision of health care..." (Becker, paragraph 0024).

16. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hume (WO 2001/25938 A1) in view of de Vries, et al. (US 2004/0006553 A1).

17. **Claim 3:**

Hume discloses the limitations as shown in the rejections above. Hume does not disclose the limitation of *entering fields of the clinical trial data in response to an electronic form presented to the clinician on the remote computing device*. However, in at least paragraphs 0041 and 0104 and figures 4d-4f, de Vries discloses that electronic forms are presented to trial investigators (doctors or nurses) on the remote computer to enter clinical trial data. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data transferring method of Hume with the data entering technique of de Vries because it provides advantages such as, "...the ability to consolidate the trial data into a single database as the trial data is being collected, thus allowing for the analysis of the data in real time..." and "...data can be validated upon entry, ultimately resulting in less time spent at the end of the trial to reconcile 'loose ends' in the data collection process..."(de Vries, paragraph 0034).

18. **Claim 4:**

The combination of Hume/de Vries discloses the limitations as shown in the rejections above. Furthermore, de Vries discloses the limitation of *validating the entered clinical trial data within the remote computing device* (see at least paragraph 0120, i.e. data values entered on the remote computer are validated). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data transferring method of Hume with the data entering technique of de Vries because it provides advantages such as, "...the ability to consolidate the trial data into a single database as the trial data is being collected, thus allowing for the analysis of the data in real time..." and "...data can be validated upon entry, ultimately resulting in less time spent at the end of the trial to reconcile 'loose ends' in the data collection process..."(de Vries, paragraph 0034).

19. Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hume (WO 2001/25938 A1) in view of de Vries, et al. (US 2004/0006553 A1) in further view of Thangaraj, et al. (US 2003/0208378 A1).

20. **Claim 5:**

The combination of Hume/de Vries discloses the limitations as shown in the rejections above. Furthermore, de Vries discloses the limitation of *the electronic form is defined and wherein the step of validating comprises validating the entered clinical trial data* (see at least paragraphs 0120-0121 and figures 4d-4f, de Vries discloses data is entered into electronic forms and as the data is entered it is validated by scripts which compare the values to accepted values). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data transferring method of Hume with the data entering technique of de Vries because it provides advantages such as, "...the ability to consolidate the trial data into a single database as the trial data is being collected, thus allowing for the analysis of the data in real time..." and "...data can be validated upon entry, ultimately resulting in less time spent at the end of the trial to reconcile 'loose ends' in the data collection process..."(de Vries, paragraph 0034).

The combination of Hume/de Vries does not explicitly disclose that the form is defined as an XML schema and that the validating is done according to an XML schema. However, in at least paragraph 0099, Thangaraj discloses that in clinical trial management, data is reformatted to a common or "normalized" XML format. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data transferring method of Hume with the data format of Thangaraj because it, "...provides for a flexible, extensible architecture in which any system can utilize the clinical trial information..." (Thangaraj, paragraph 0101).

21. Claim 6:

The combination of Hume/de Vries/Thangaraj discloses the limitations as shown in the rejections above. Furthermore, Hume, as shown, discloses the following limitations:

- *comparing entered data against a corresponding edit specification* (see at least page 9, lines 11-22, i.e. entered data is compared to known preselected characteristics for a specific type of data to be collected to determine if the data is within acceptable limits);
- *receiving clinician input in response to a determination that the entered data does not conform to the corresponding edit specification* (see at least page 9, lines 11-22, i.e. user is allowed to enter new data in response to a notification of non-acceptance of previously entered data).

The combination of Hume/de Vries does not explicitly disclose that the data is compared in an XML schema. However, in at least paragraph 0099, Thangaraj discloses that in clinical trial management, data is reformatted to a common or "normalized" XML format. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data transferring method of Hume with the data format of Thangaraj because it, "...provides for a flexible, extensible architecture in which any system can utilize the clinical trial information..." (Thangaraj, paragraph 0101).

22. Claim 7:

The combination of Hume/de Vries/Thangaraj discloses the limitations as shown in the rejections above. Furthermore, Hume discloses the limitation of *receiving corrected data that adheres to the corresponding edit specification* (see at least page 9, lines 11-23, i.e. new data entered is deemed acceptable).

23. Claim 8:

The combination of Hume/de Vries/Thangaraj discloses the limitations as shown in the rejections above. Furthermore, de Vries discloses the limitation of *receiving validation annotation*

information recorded with the entered data to explain the mis-comparison of the entered data relative to the corresponding edit specification (see at least paragraphs 0121-0122, i.e. if data is outside exception limits, the system asks trial investigator to reply and the exception record is added to the transaction). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data transferring method of Hume with the data entering technique of de Vries because it provides advantages such as, "...the ability to consolidate the trial data into a single database as the trial data is being collected, thus allowing for the analysis of the data in real time..." and "...data can be validated upon entry, ultimately resulting in less time spent at the end of the trial to reconcile 'loose ends' in the data collection process..."(de Vries, paragraph 0034).

24. Claim 9:

The combination of Hume/de Vries/Thangaraj discloses the limitations as shown in the rejections above. Furthermore, de Vries discloses the limitation of *receiving validation status information recorded with the entered data to indicate the status of further investigation regarding the mis-comparison of the entered data relative to the corresponding edit specification* (see at least paragraphs 0123-0124 and figure 5, i.e. when data is determined to be an exception, an option is offered to complete exception data immediately or later, and when the entering of exception data is chosen to be done at a later time, the exception is queued and status will be shown to the user). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data transferring method of Hume with the data entering technique of de Vries because it provides advantages such as, "...the ability to consolidate the trial data into a single database as the trial data is being collected, thus allowing for the analysis of the data in real time..." and "...data can be validated upon entry, ultimately resulting in less time spent at the end of the trial to reconcile 'loose ends' in the data collection process..."(de Vries, paragraph 0034).

25. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hume (WO 2001/25938 A1) in view of Thangaraj, et al. (US 2003/0208378 A1).

26. **Claim 11:**

Hume, as shown, discloses the following limitations:

- *receiving clinical trial data from an examining clinician using a remote computer system* (see at least page 9, lines 11-22, i.e. remote computer system receives clinical trial data from a remote site by a clinician)*;*
- *determining whether the remote computer system is presently communicatively coupled to a central system* (see at least page 3, lines 16-22, i.e. remote site detects if a network connection is present with central site)*;*
- *forwarding the clinical trial data to the central system in response to a determination that the remote computer system is presently coupled to the central system* (see at least page 6, lines 7-14, i.e. if network connection is established between the remote user site and central site, data is transmitted to central site in the form of data packets)*;*
- *spooling the clinical trial data on the remote computer system in response to a determination that the remote computer system is not presently coupled to the central system* (see at least page 6, lines 15-26, i.e. if the network connection cannot be established or is intermittent, the data is stored at the remote site and the system continuously attempts to establish or restore a network connection) *wherein spooling includes securing the clinical trial data on the remote computer system to preclude unauthorized access thereto* (see at least page 8, lines 24-26, i.e. data stored on local system is encrypted)*;*
- *transmitting the spooled clinical trial data to the central system in response to a subsequent determination that the remote computer system is again coupled to the central system* (see at least page 6, lines 7-14, i.e. if network connection is established between the remote user site and central site, data is transmitted to central site in the form of data packets).

Hume does not explicitly disclose the clinical trial data is sent using XML messages. However, in at least paragraph 0099, Thangaraj discloses that in clinical trial management, data is reformatted to a common or "normalized" XML format. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data transferring method of Hume with the data format of Thangaraj because it, "...provides for a flexible, extensible architecture in which any system can utilize the clinical trial information..." (Thangaraj, paragraph 0101).

27. Claims 12-17, 26-29, and 35-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hume (WO 2001/25938 A1) in view of de Vries, et al. (US 2004/0006553 A1) in further view of Becker, et al. (US 2002/0019749 A1).

28. **Claim 12:**

Hume, as shown, discloses the following limitations:

- *a remote computer system for use by an examining clinician* (see at least page 9, lines 11-22, i.e. remote user enters clinical trial data from a remote site)
- *a remote communication link for coupling the remote computer system to a central system* (see at least page 10, lines 8-17, i.e. communication link between remote and central sites is established as internet, LAN, WAN, intranet, dial-up, VPN, etc.);
- *a remote secured store for temporary storage of the clinical trial data until transmission of the clinical trial data to the central system may be accomplished* (see at least page 6, lines 15-26, i.e. remote site can temporarily store data until network connection with central site is established and data is transmitted);
- *a central system for centralized storage, analysis and reporting of the clinical trial data* (see at least page 15, lines 3-20, i.e. central system organizes, stores, and audits the data transferred from the remote site and allows users to view and print audit reports);

- *a central communication link for coupling the central system to the remote computer system* (see at least page 10, lines 8-17, i.e. communication link between remote and central sites is established as internet, LAN, WAN, intranet, dial-up, VPN, etc.)*;*
- *a central secured store for storage of the clinical trial data received from the remote computer system* (see at least page 15, lines 3-20, i.e. central system stores the encrypted data transferred from the remote site)*;*
- *a communication medium coupled to the remote communication link and coupled to the central communication link for exchanging the clinical trial data between the remote computer system and the central system* (see at least page 10, lines 8-17, i.e. communication connection can be made through dedicated network line, such as a T1 or ISDN line, dial-up, or wireless).

Hume does not explicitly disclose the following limitations, but de Vries as shown does:

- *form data entry components for presenting a form to the clinician and for receiving clinical trial data as responses to the presented form* (see at least paragraphs 0041 and 0104 and figures 4d-4f, i.e. electronic forms are presented to trial investigators (doctors or nurses) on the remote computer to enter clinical trial data)*;*

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data transferring method of Hume with the data entering technique of de Vries because it provides advantages such as, "…the ability to consolidate the trial data into a single database as the trial data is being collected, thus allowing for the analysis of the data in real time…" and "…data can be validated upon entry, ultimately resulting in less time spent at the end of the trial to reconcile 'loose ends' in the data collection process…"(de Vries, paragraph 0034).

The combination of Hume/de Vries does not explicitly disclose the following limitations, but Becker as shown does:

- *hand drawn data entry components to receive digitized images of hand drawn information as clinical trial data* (see at least paragraphs 0039 and 0080, Becker discloses a clinician can enter a handwriting image on a handheld computer tablet using pen strokes);

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data transferring method of Hume with the digitized handwriting technique of Becker because it allows the process to, "…automate healthcare administrative tasks such as completion of forms, requisitions, transmittal memos, etc. to improve the accuracy of information and reduce errors in the provision of health care…" (Becker, paragraph 0024).

29. Claim 13:

The combination of Hume/de Vries/Becker discloses the limitations as shown in the rejections above. Furthermore, de Vries discloses the limitation of *the remote computer system comprises a hand held computing device* (see at least paragraph 0063). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data transferring method of Hume with the data entering technique of de Vries because it provides advantages such as, "…the ability to consolidate the trial data into a single database as the trial data is being collected, thus allowing for the analysis of the data in real time…" and "…data can be validated upon entry, ultimately resulting in less time spent at the end of the trial to reconcile 'loose ends' in the data collection process…"(de Vries, paragraph 0034).

30. Claim 14:

The combination of Hume/de Vries/Becker discloses the limitations as shown in the rejections above. Furthermore, Becker discloses the limitation of *the hand held computing device comprises a tablet PC* (see at least paragraph 0080). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data transferring method of Hume with the digitized handwriting technique of Becker because it allows the process to, "…automate healthcare administrative tasks such as completion of forms, requisitions, transmittal

memos, etc. to improve the accuracy of information and reduce errors in the provision of health care…" (Becker, paragraph 0024).

31. Claim 15:

The combination of Hume/de Vries/Becker discloses the limitations as shown in the rejections above. Furthermore, Becker discloses the limitation of *the hand held computing device comprises a laptop computer* (see at least paragraph 0079). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data transferring method of Hume with the digitized handwriting technique of Becker because it allows the process to, "…automate healthcare administrative tasks such as completion of forms, requisitions, transmittal memos, etc. to improve the accuracy of information and reduce errors in the provision of health care…" (Becker, paragraph 0024).

32. Claim 16:

The combination of Hume/de Vries/Becker discloses the limitations as shown in the rejections above. Furthermore, Becker discloses the limitation of *the remote computer system comprises a desktop computing device* (see at least paragraph 0079). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data transferring method of Hume with the digitized handwriting technique of Becker because it allows the process to, "…automate healthcare administrative tasks such as completion of forms, requisitions, transmittal memos, etc. to improve the accuracy of information and reduce errors in the provision of health care…" (Becker, paragraph 0024).

33. Claim 17:

The combination of Hume/de Vries/Becker discloses the limitations as shown in the rejections above. Furthermore, Hume discloses the limitation of *the communication medium comprises a wireless communication medium* (see at least page 10, lines 8-17).

34. Claim 26:

Hume, as shown, discloses the following limitations:

- *a remote computer system for use by an examining clinician* (see at least page 9, lines 11-22, i.e. remote user enters clinical trial data from a remote site)
- *a remote communication link for coupling the remote computer system to a central system* (see at least page 10, lines 8-17, i.e. communication link between remote and central sites is established as internet, LAN, WAN, intranet, dial-up, VPN, etc.)*;*
- *a remote secured store for temporary storage of the clinical trial data until transmission of the clinical trial data to the central system may be accomplished* (see at least page 6, lines 15-26, i.e. remote site can temporarily store data until network connection with central site is established and data is transmitted)*;*

Hume does not explicitly disclose the following limitations, but de Vries as shown does:

- *form data entry components for presenting a form to the clinician and for receiving clinical trial data as responses to the presented form* (see at least paragraphs 0041 and 0104 and figures 4d-4f, i.e. electronic forms are presented to trial investigators (doctors or nurses) on the remote computer to enter clinical trial data)*;*

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data transferring method of Hume with the data entering technique of de Vries because it provides advantages such as, "…the ability to consolidate the trial data into a single database as the trial data is being collected, thus allowing for the analysis of the data in real time…" and "…data can be validated upon entry, ultimately resulting in less time spent at the end of the trial to reconcile 'loose ends' in the data collection process…"(de Vries, paragraph 0034).

The combination of Hume/de Vries does not explicitly disclose the following limitations, but Becker as shown does:

- *hand drawn data entry components to receive digitized images of hand drawn information as clinical trial data* (see at least paragraphs 0039 and 0080, Becker discloses a clinician can enter a handwriting image on a handheld computer tablet using pen strokes);

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data transferring method of Hume with the digitized handwriting technique of Becker because it allows the process to, "…automate healthcare administrative tasks such as completion of forms, requisitions, transmittal memos, etc. to improve the accuracy of information and reduce errors in the provision of health care…" (Becker, paragraph 0024).

35. Claim 27:

The combination of Hume/de Vries/Becker discloses the limitations as shown in the rejections above. Furthermore, de Vries discloses the limitation of *the hand drawn data entry component is operable to receive digitized hand drawn images from a paper document scanning device communicably linked to the remote computer system* (see at least paragraph 0017, i.e. handwritten trial data reports are placed into digital form with the use of an electronic scanner. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data transferring method of Hume with the data entering technique of de Vries because it provides advantages such as, "…the ability to consolidate the trial data into a single database as the trial data is being collected, thus allowing for the analysis of the data in real time…" and "…data can be validated upon entry, ultimately resulting in less time spent at the end of the trial to reconcile 'loose ends' in the data collection process…"(de Vries, paragraph 0034).

De Vries does not explicitly disclose the limitation of *the hand drawn data entry component is operable to receive digitized hand drawn images from an electronic digitizing tablet device communicably linked to the remote computer system.* However, in at least paragraphs 0077-0080, Becker discloses a clinician can enter a handwriting image on a handheld computer tablet using pen strokes and the tablet is communicably linked to a clinic server. It would have been

obvious to one of ordinary skill in the art at the time of the invention to combine the data transferring method of Hume with the digitized handwriting technique of Becker because it allows the process to, "...automate healthcare administrative tasks such as completion of forms, requisitions, transmittal memos, etc. to improve the accuracy of information and reduce errors in the provision of health care..." (Becker, paragraph 0024).

36. Claim 28:

The combination of Hume/de Vries/Becker discloses the limitations as shown in the rejections above. Furthermore, de Vries discloses the limitation of *the remote computer system further comprises data entry validation components operable for validating data entered by the clinician by comparing entered data against a corresponding edit specification and for notifying the clinician when the data entry is invalid* (see at least paragraphs 0120-0123, i.e. clinical trial data is entered on forms at the remote system, validated by comparing the data to exception limits, and if the data is outside of the exception limits, the system presents the trial investigator (doctor or nurse) with an alert that the data is out of exception limits). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data transferring method of Hume with the data entering technique of de Vries because it provides advantages such as, "...the ability to consolidate the trial data into a single database as the trial data is being collected, thus allowing for the analysis of the data in real time..." and "...data can be validated upon entry, ultimately resulting in less time spent at the end of the trial to reconcile 'loose ends' in the data collection process..."(de Vries, paragraph 0034).

37. Claim 29:

The combination of Hume/de Vries/Becker discloses the limitations as shown in the rejections above. Furthermore, de Vries discloses the limitation of *the data entry validation component is further operable to prompt the clinician for reentry of corrected data and receive said corrected data and further operable to prompt the clinician to alternatively enter annotated data explaining*

why data need not be corrected and operable to receive said annotated data (see at least paragraphs 0120-0123, i.e. when entered data is outside of exception limits the program alerts the user to enter additional data to insure out-of-range data is in fact correct). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data transferring method of Hume with the data entering technique of de Vries because it provides advantages such as, "...the ability to consolidate the trial data into a single database as the trial data is being collected, thus allowing for the analysis of the data in real time..." and "...data can be validated upon entry, ultimately resulting in less time spent at the end of the trial to reconcile 'loose ends' in the data collection process..."(de Vries, paragraph 0034).

38. Claim 35:

The combination of Hume/de Vries/Becker discloses the limitations as shown in the rejections above. Furthermore, Hume, as shown, discloses the following limitations:

- *a central system for centralized storage, analysis and reporting of the clinical trial data* (see at least page 15, lines 3-20, i.e. central system organizes, stores, and audits the data transferred from the remote site and allows users to view and print audit reports);
- *a central communication link for coupling the central system to the remote computer system* (see at least page 10, lines 8-17, i.e. communication link between remote and central sites is established as internet, LAN, WAN, intranet, dial-up, VPN, etc.);
- *a central secured store for storage of the clinical trial data received from the remote computer system* (see at least page 15, lines 3-20, i.e. central system stores the encrypted data transferred from the remote site);
- *a communication medium coupled to the remote communication link and coupled to the central communication link for exchanging the clinical trial data between the remote computer system and the central system* (see at least page 10, lines 8-17, i.e. communication

connection can be made through dedicated network line, such as a T1 or ISDN line, dial-up, or wireless).

39. Claim 36:

The combination of Hume/de Vries/Becker discloses the limitations as shown in the rejections above. Furthermore, Hume discloses the limitation of *the communication medium comprises a wireless communication medium* (see at least page 10, lines 8-17).

40. Claim 37:

The combination of Hume/de Vries/Becker discloses the limitations as shown in the rejections above. Furthermore, Hume discloses the limitation of *a central data entry validation component operable to notify the remote computer system with a data invalidation error when data is determined to be invalid* (see at least page 9, lines 11-22, i.e. data entered at the remote site is determined unacceptable by the central site and message is displayed at remote site notifying user of unacceptability of data).

41. Claim 38:

The combination of Hume/de Vries/Becker discloses the limitations as shown in the rejections above. Furthermore, Hume discloses the limitation of *a client certificate component operable to generate a client certificate to secure submitted data from unauthorized assets* (see at least page 7, line 8 – page 9, line 10, i.e. remote users must log into system with user id and password, remote users are assigned roles that limit their access rights, and patient data packets use public and private keys to protect a patient's privacy).

42. Claim 39:

The combination of Hume/de Vries/Becker discloses the limitations as shown in the rejections above. Furthermore, Hume discloses the limitation of *the client certificate component is*

combined with a data encryption technique (see at least page 7, line 8 – page 9, line 10, i.e. remote users must log into system with user id and password, remote users are assigned roles that limit their access rights, patient data packets use public and private keys to protect a patient's privacy, and all data stored on the local system's hard drive is encrypted using encryption algorithms).

43. Claims 18 and 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hume (WO 2001/25938 A1) in view of de Vries, et al. (US 2004/0006553 A1) in further view of Becker, et al. (US 2002/0019749 A1) in further view of Thangaraj, et al. (US 2003/0208378 A1).

44. Claim 18:

The combination of Hume/de Vries/Becker discloses the limitations as shown in the rejections above. The combination of Hume/de Vries/Becker does not disclose the limitation of *the clinical trial data comprises XML messages*. However, in at least paragraph 0099, Thangaraj discloses that in clinical trial management, data is reformatted to a common or "normalized" XML format. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data transferring method of Hume with the data format of Thangaraj because it, "…provides for a flexible, extensible architecture in which any system can utilize the clinical trial information…" (Thangaraj, paragraph 0101).

45. Claim 30:

The combination of Hume/de Vries/Becker discloses the limitations as shown in the rejections above. Furthermore, de Vries discloses the limitation of *a report selection component operable to receive a report selection from the clinician and further operable to initiate retrieval of the appropriate re-formatted clinical data responsive to and in accordance with the report selection* (see at least paragraphs 0149-0163, i.e. once the trial monitor or trial administrator logs in, they have access to all kinds of analysis and reports that can be selected and generated by

reformatting the data to many different formats). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data transferring method of Hume with the data entering technique of de Vries because it provides advantages such as, "…the ability to consolidate the trial data into a single database as the trial data is being collected, thus allowing for the analysis of the data in real time…" and "…data can be validated upon entry, ultimately resulting in less time spent at the end of the trial to reconcile 'loose ends' in the data collection process…"(de Vries, paragraph 0034).

The combination of Hume/de Vries/Becker does not explicitly disclose the clinical trial data is entered into an XML format. However, in at least paragraph 0099, Thangaraj discloses that in clinical trial management, data is reformatted to a common or "normalized" XML format. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine data transferring method of Hume with the data format of Thangaraj because it, "…provides for a flexible, extensible architecture in which any system can utilize the clinical trial information…" (Thangaraj, paragraph 0101).

46. Claim 31:

The combination of Hume/de Vries/Becker/Thangaraj discloses the limitations as shown in the rejections above. Furthermore, de Vries discloses the limitation of *the remote computer system comprises a hand held computing device* (see at least paragraph 0063). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data transferring method of Hume with the data entering technique of de Vries because it provides advantages such as, "…the ability to consolidate the trial data into a single database as the trial data is being collected, thus allowing for the analysis of the data in real time…" and "…data can be validated upon entry, ultimately resulting in less time spent at the end of the trial to reconcile 'loose ends' in the data collection process…"(de Vries, paragraph 0034).

47. Claim 32:

The combination of Hume/de Vries/Becker/Thangaraj discloses the limitations as shown in the rejections above. Furthermore, Becker discloses the limitation of *the hand held computing device comprises a tablet PC* (see at least paragraph 0080). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data transferring method of Hume with the digitized handwriting technique of Becker because it allows the process to, "…automate healthcare administrative tasks such as completion of forms, requisitions, transmittal memos, etc. to improve the accuracy of information and reduce errors in the provision of health care…" (Becker, paragraph 0024).

48. Claim 33:

The combination of Hume/de Vries/Becker/Thangaraj discloses the limitations as shown in the rejections above. Furthermore, Becker discloses the limitation of *the hand held computing device comprises a laptop computer* (see at least paragraph 0079). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data transferring method of Hume with the digitized handwriting technique of Becker because it allows the process to, "…automate healthcare administrative tasks such as completion of forms, requisitions, transmittal memos, etc. to improve the accuracy of information and reduce errors in the provision of health care…" (Becker, paragraph 0024).

49. Claim 34:

The combination of Hume/de Vries/Becker/Thangaraj discloses the limitations as shown in the rejections above. Furthermore, Becker discloses the limitation of *the remote computer system comprises a desktop computing device* (see at least paragraph 0079). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data transferring method of Hume with the digitized handwriting technique of Becker because it allows

the process to, "...automate healthcare administrative tasks such as completion of forms, requisitions, transmittal memos, etc. to improve the accuracy of information and reduce errors in the provision of health care..." (Becker, paragraph 0024).

50. Claims 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Vries, et al. (US 2004/0006553 A1) in view of Becker, et al. (US 2002/0019749 A1) in further view of Thangaraj, et al. (US 2003/0208378 A1).

51. **Claim 19:**

De Vries, as shown, discloses the following limitations:

- *presenting to an examining clinician an electronic clinician data entry form on a remote display device of a remote computing system, said form having a set of data entry fields designed for receiving entry of a set of clinical trial data to be input by the examining clinician* (see at least paragraphs 0041 and 0104 and figures 4d-4f, i.e. electronic forms are presented to trial investigators (doctors or nurses) on the remote computer to enter clinical trial data);

De Vries does not explicitly disclose the following limitations, but Becker as shown does:

- *presenting to the examining clinician a prompt for selecting an option for manual entry of information* (see at least paragraph 0109 and figure 9, i.e. clinician can select a write pad button for handwriting image capture from the user);
- *presenting to the examining clinician an indicator to begin manual entry of the digital information* (see at least paragraph 0109 and figure 9, i.e. a screen for handwriting image capture is revealed once clinician touches write pad button).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data entering method of de Vries with the digitized handwriting technique of Becker because it allows the process to, "...automate healthcare administrative tasks such as completion of forms, requisitions, transmittal memos, etc. to improve the accuracy of information and reduce errors in the provision of health care..." (Becker, paragraph 0024).

The combination of de Vries/Becker does not explicitly disclose that the form is defined as an XML schema. However, in at least paragraph 0099, Thangaraj discloses that in clinical trial management, data is reformatted to a common or "normalized" XML format. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data entering method of de Vries with the data format of Thangaraj because it, "...provides for a flexible, extensible architecture in which any system can utilize the clinical trial information..." (Thangaraj, paragraph 0101).

52. Claim 20:

The combination of de Vries/Becker/Thangaraj discloses the limitations as shown in the rejections above. Furthermore, Becker discloses the limitation of *presenting an option for manual entry utilizing a digital paper document scanner or manual entry utilizing an electronic digitizing tablet* (see at least paragraph 0109 and figure 9, i.e. clinician can select a write pad button on the electronic tablet for handwriting image capture from the user). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data entering method of de Vries with the digitized handwriting technique of Becker because it allows the process to, "...automate healthcare administrative tasks such as completion of forms, requisitions, transmittal memos, etc. to improve the accuracy of information and reduce errors in the provision of health care..." (Becker, paragraph 0024).

53. Claim 21:

The combination of de Vries/Becker/Thangaraj discloses the limitations as shown in the rejections above. Furthermore, de Vries, as shown, discloses the following limitations:

- *presenting to the examining clinician an invalid form data field entry indicator responsive to a validation processing computing component residing on the remote computing system and operable to compare clinician entered data with a corresponding edit specification* (see at

least paragraphs 0120-0123, i.e. clinical trial data is entered on forms at the remote system, validated by comparing the data to exception limits, and if the data is outside of the exception limits, the system presents the trial investigator (doctor or nurse) with an alert that the data is out of exception limits) *and presenting to the examining clinician a reentry prompt where the clinician can select to reenter corrected form data* (see at least paragraphs 0120-0123, i.e. when the alert is presented the system requests the trial investigator enter additional or corrected data);

- *presenting a reentry field responsive to a selection of reentry* (see at least paragraphs 0120-0123, i.e. when the alert is presented the system requests the trial investigator enter additional or corrected data).

De Vries does not explicitly disclose the clinical trial data is entered into an XML schema. However, in at least paragraph 0099, Thangaraj discloses that in clinical trial management, data is reformatted to a common or "normalized" XML format. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data entering method of de Vries with the data format of Thangaraj because it, "...provides for a flexible, extensible architecture in which any system can utilize the clinical trial information..." (Thangaraj, paragraph 0101).

54. Claim 22:

The combination of de Vries/Becker/Thangaraj discloses the limitations as shown in the rejections above. Furthermore, de Vries, as shown, discloses the following limitations:

- *presenting an optional annotation prompt in the alternative for entry of annotated entered data with entered explanation why the entry flagged as invalid is acceptable* (see at least paragraphs 0120-0123, i.e. when entered data is outside of exception limits the program alerts the user to enter additional data to insure out-of-range data is in fact correct);

- *presenting an annotated reentry field responsive to a selection of annotated reentry* (see at least paragraphs 0120-0123, i.e. when entered data is outside of exception limits the program alerts the user to enter additional data to insure out-of-range data is in fact correct).

55. Claim 23:

The combination of de Vries/Becker/Thangaraj discloses the limitations as shown in the rejections above. Furthermore, Becker discloses the limitation of *presenting to the examining clinician a submission prompt for selection to indicate that data entry is completed and submission is requested* (see at least paragraph 0109, i.e. accept button is presented to physician to accept data entered using remote computer for incorporation into patient record at central computer). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data entering method of de Vries with the digitized handwriting technique of Becker because it allows the process to, "...automate healthcare administrative tasks such as completion of forms, requisitions, transmittal memos, etc. to improve the accuracy of information and reduce errors in the provision of health care..." (Becker, paragraph 0024).

56. Claim 24:

The combination of de Vries/Becker/Thangaraj discloses the limitations as shown in the rejections above. Furthermore, de Vries, as shown, discloses the following limitations:

- *presenting to a requesting user a report prompt for selecting generation of a report of entered clinical trial data* (see at least paragraph 0149 and 0160, i.e. trial monitor or trial administrator is prompted to enter username and password to have access to reports of trial data);
- *presenting to the requesting user responsive to a selection of the report prompt, a report of the appropriate clinical trial data reformatted according to the output requirements corresponding to the report prompt selected* (see at least paragraphs 0149-0163, i.e. once the trial monitor or trial administrator logs in, they have access to all kinds of analysis and reports that can be generated by reformatting the data to many different formats).

De Vries does not explicitly disclose the clinical trial data is entered into an XML format. However, in at least paragraph 0099, Thangaraj discloses that in clinical trial management, data is reformatted to a common or "normalized" XML format. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data entering method of de Vries with the data format of Thangaraj because it, "...provides for a flexible, extensible architecture in which any system can utilize the clinical trial information..." (Thangaraj, paragraph 0101).

57. Claim 25:

The combination of de Vries/Becker/Thangaraj discloses the limitations as shown in the rejections above. Furthermore, de Vries discloses the limitation of *the report is reformatted in accordance with requirements of a select regulatory agency corresponding to the report prompt selected* (see at least paragraph 0163, i.e. templates for various kinds of reports are available through the system and certain reports laid out using certain templates can be electronically transferred to governmental regulatory board). De Vries does not explicitly disclose the clinical trial data is in an XML format. However, in at least paragraph 0099, Thangaraj discloses that in clinical trial management, data is reformatted to a common or "normalized" XML format. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the data entering method of de Vries with the data format of Thangaraj because it, "...provides for a flexible, extensible architecture in which any system can utilize the clinical trial information..." (Thangaraj, paragraph 0101).

Conclusion

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **JOSEPH BURGESS** whose telephone number is **(571)270-5547.** The Examiner can normally be reached on

Monday-Friday, 9:00am-5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **JAMES REAGAN** can be reached at (**571)272-6710**.

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